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ART 34 AMDT

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CLAIMS

1. A process of purification of an otherwise pure nona- or
5 decapeptide from residual organic solvent, comprising the following steps:
- dissolving the nona- or decapeptide in a dissolution solvent mixture comprising water and at least one alcohol selected from methanol, ethanol, propanol, isopropanol;
 - 10 - adding the solution of the nona- or decapeptide in said solvent mixture to a vigorously stirred precipitation solvent mixture essentially consisting of one or several polar compounds selected from methyl acetate, ethyl acetate, methyl propionate, ethyl propionate, butyl acetate, isobutyl acetate,
 - 15 t-butyl acetate, ethyl formate, propyl formate, isopropyl formate, and one or several non-polar compounds selected from hexane, heptane, octane, cyclohexane, methylcyclohexane, and, optionally, of up to 5% of acetic or propionic acid;
 - isolating the precipitated nona- or decapeptide;
 - 20 - washing the isolated nona- or decapeptide with one or a mixture of said polar compounds or a solvent or solvent mixture of similar polarity,
 - drying the washed nona- or decapeptide,
 - 25 with the proviso that the water content of said solvent mixture comprising water and at least one alcohol is below 8% (v/v), and that the volume ratio of the dissolution solvent mixture and the precipitation solvent mixture is 1:10 or more.
2. The process of claim 1, wherein the water content of said
30 solvent mixture comprising water and at least one alcohol is below 5% (v/v).
3. The process of claim 1, wherein said nona- or decapeptide is an LHRH antagonist.

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4. The process of claim 3, wherein said nona- or decapeptide is Ac-D-2Nal-D-4ClPhe-D-3Pal-Ser-MeTyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH₂ (I).

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5. The process of claim 4, wherein Ac-D-2Nal-D-4ClPhe-D-3Pal-Ser-MeTyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH₂ (I) is obtained in form of the monoacetate.

10 6. The process of claim 1, wherein the volume ratio of the dissolution solvent mixture and the precipitation solvent mixture is at least 15.

15 7. The process of claim 1, wherein the alcohol of the dissolution solvent mixture is ethanol.

8. The process of claim 1, wherein the polar component of the precipitation solvent mixture is ethyl acetate.

20 9. The process of claim 1, wherein the non-polar component of the precipitation solvent mixture is heptane.

10. The monoacetate of Ac-D-2Nal-D-4ClPhe-D-3Pal-Ser-MeTyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH₂.

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